VERMONT

Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 09/08/09

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Virginia Hood, M.D.
Norman Ward, M.D.
Kathleen Boland, Pharm.D.
Stuart Graves, M.D.
Cheryl Gibson, M.D

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Vicki Loner, OVHA
Jennifer Mullikin, OVHA
Nancy Hogue, Pharm.D. (MHP)
Robin Farnsworth, OVHA

Guests:

Glenn E. Dooley, Sr, Sanofi-Aventis
Christine Dube, MedImmune
Rod Francisco, Forest
Doug Kenyon, MedImmune
James Kokoszyna, Allergan
Carl Marchand, AstraZeneca
Chris Michaels, Elan
Steven McRae, Genentech
Danielle Moon, Merck
Tim Nies, GSK
Angelo Valeri, Novartis

Michael Scovner, M.D. Chair, called the meeting to order at 7:07 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The June 2009 meeting minutes were accepted as printed.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Ann Rugg – former Deputy Director, OVHA*

- New OVHA Deputy Director: Vicki Loner was introduced as the new Deputy Director, replacing Ann Rugg who retired effective September 1st.
- Expansion of Specialty Pharmacy**:** The Specialty Pharmacy program is being expanded to include select oral oncology products (more discussion to come later in meeting).

4. Medical Director Update: *New Medical Director, Dr. Michael Farber to join OVHA beginning October 1st.*

- Clinical Programs Update: No updates to report.
- Prescriber Comments: No prescriber comments received.

5. Follow-up items from Previous Meeting: *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- No follow-up items

6. Clinical Update: Drug Reviews: *Diane Neal, R.Ph.(MHP)*
(Public comment prior to Board action)
Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

Abbreviated New Drug Reviews

- Apriso® (mesalamine) Extended Release Capsule: Recommended for addition to the PDL as preferred.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Kapidex® (dexlansoprazole) Capsule: Recommended for addition to the PDL as preferred with a quantity limit of one capsule per day.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above (with one opposed vote) and requested that communications to providers explain that the Board has determined that all drugs within the proton pump inhibitor class are efficacious and that preferred status decisions are thus based on net cost.

- Moxatag® (amoxicillin) Extended Release Tablet: It was recommended that coverage would require PA with the criteria for approval being that the prescriber must provide a clinically valid reason for its use. In addition, a quantity limit of one tablet per day was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Prandimet® (repaglinide/metformin) Tablet: It was recommended that coverage would require PA with the criteria for approval being that the patient has been started and stabilized on the medication or on stable doses of the separate agents or the patient has had an inadequate response with repaglinide monotherapy.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Prilosec® (omeprazole magnesium) Delayed Release Suspension Powder Packet: It was recommended that coverage would require PA with the criteria for approval being that the patient has a requirement for a liquid dosage form. In addition, a quantity limit of two packs per day was recommended.

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

Full Drug Reviews

- Banzel® (rufinamide) Tablet: It was recommended that coverage would require PA with the criteria for approval being that the diagnosis or indication is treatment of Lennox-Gastaut Syndrome and the patient has had a documented side effect, allergy, treatment failure/inadequate response or a contraindication to at least one preferred anticonvulsant (topiramate, lamotrigine, valproic acid). In addition, a quantity limit of 8 tablets per day of the 400 mg strength tablets and 16 tablets per day of the 200 mg strength tablets was recommended.

Public Comment: No public comment.

Board Decision: The Board approved adding Banzel® as prior authorization required but requested that the patient has had trials of at least two preferred anticonvulsants.

- Uloric® (febuxostat) Tablet: It was recommended that coverage would require PA with the criteria for approval being that the diagnosis or indication is treatment of gout and the patient has had a documented side effect, allergy, treatment failure or a contraindication to allopurinol. In addition, a quantity limit of one tablet per day of the 40 mg strength tablet was recommended.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above but requested that treatment failure be defined as an inability to reduce serum uric acid to < 6 mg/dL with allopurinol doses of 600 mg/day taken consistently and that it be noted that renal impairment is not considered a contraindication to allopurinol use. The Board also requested that a RetroDUR on allopurinol use be conducted to assess compliance.

- Vectical® (calcitriol) Topical Ointment: It was recommended that coverage would require PA with the criteria for approval being that the patient is ≥ 18 years of age and the patient has a diagnosis of mild to moderate plaque psoriasis and the patient has demonstrated inadequate response, adverse reaction or contraindication to calcipotriene. In addition, a quantity limit of 200 g/week (2 tubes/week) was recommended.

Public Comment: No public comment.

Board Decision: The Board requested that a dermatologist be consulted for recommendations regarding step therapy and required topical treatments before approval. The decision on PDL placement was thus deferred until the next meeting.

7. **Review of Newly-Developed/Revised Clinical Coverage Criteria:** *Diane Neal, R.Ph, (MHP)*
(Public comment prior to Board action)

- Botulinum Toxins:
The FDA released an information bulletin regarding the botulinum toxins. A generic renaming was required of all products to try to distinguish between the products which also have very different dosing recommendations. The clinical criteria manual and PDL will be updated to reflect these new generic names.

Public Comment: No public comment.

Board Decision: None needed.

- Gastrointesinals: Proton Pump Inhibitors:
  It was recommended that in addition to the new drugs previously discussed (Kapidex® and Prilosec® Powder Packet) that the following changes are made in this drug category. Prevacid® will move to PA required. Current users will be grandfathered until the end of the year at which time they will need to have been moved to a preferred product. Letters will be sent to prescribers with a list attached of patients who will need a new prescription for a preferred product. For approval of a non-preferred tablet or capsule, patients will need to have tried Protonix®, Prilosec® OTC and Kapidex®

Public Comment: No public comment.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

- Specialty Pharmacy Expansion-Select Oral Oncology:
  The legislature requested that oral oncology be required to be obtained through Specialty Pharmacy in order to achieve further pharmacy program cost savings. The letter being sent to prescribers was shared with the Board. The category specific order form was also presented.

Public Comment: No public comment.

Board Decision: None needed.

- Synagis®-New AAP guidelines (seeRetroDUR):
  The American Academy of Pediatrics recently released updated guidelines regarding the use of Synagis® for the prevention of RSV. The policy statement and an article summarizing the guideline changes from prior years were distributed to the DUR Board members. This issue was discussed further in the RetroDUR discussion below.

Public Comment: No Public Comment.

Board Decision: None needed.

8. Drug Classes – Annual Review:
(Public comment prior to Board action)

No class reviews this month

9. RetroDUR: *Diane Neal, R.Ph, (MHP)*

- Synagis®- Utilization data along with prior authorization requests were evaluated from October 1, 2008 to April 30, 2009. The results indicate appropriate utilization based on the current approval criteria. Between November 1, 2008 and April 30, 2009, there were a total of 646 paid claims for Synagis®. In April, 2009, there were 132 paid claims submitted for 92 unique utilizers. The total plan cost of Synagis® administration during the 2008-2009 RSV season was $1,061,054. If the 6th Synagis® dose, administered in April, is eliminated, the plan may save approximately $216,810. Furthermore, of the approved requests, 8 members born between 32 and 35 weeks of gestation were between the ages of 3 and 6 months. While these approvals are in accordance with the approval criteria in place at the

time, they will not be warranted if the criteria are modified in response to the 2009 AAP update. Assuming these patients received 5 Synagis® doses per season, the plan could save an additional $65,700 with the revision of the current approval criteria. The total anticipated cost savings of the recommended revised approval criteria is expected to be approximately $300,577 per each RSV season.

Based on the information presented in this quality assurance analysis as well as a review of the revised 2009 AAP guidelines, the following updated approval criteria is recommended:

Criteria for Approval**:** (season to run from November 1, 2009 to March 31, 2010)

- Infants born at 28 weeks of gestation or earlier (i.e., ≤ 28 weeks, 6 days) and under twelve months of age at the start of the RSV season.
- Infants born at 29-32 weeks (i.e., between 29 weeks, 0 days and 31 weeks, 6 days) of gestation and under 6 months of age at the start of the RSV season.
- Infants born at 32-35 weeks (i.e., between 32 weeks, 0 day and 34 weeks, 6 days) of gestation and under 3 months of age at the start of RSV season (or at the time of PA submission, whichever is later) who has one of the following risk factors:
    - Child Care Attendance
    - Siblings who are less than 5 years of age
- Children under 24 months of age with chronic lung disease of prematurity (bronchopulmonary dysplasia) who have received medical therapy (supplemental oxygen, bronchodilator, diuretic or corticosteroid therapy) within 6 months prior to the start of RSV season.
- Children under 24 months of age with hemodynamically significant cyanotic and acyanotic congenital heart disease:
    - Receiving medication to control congestive heart failure
    - With moderate to severe pulmonary hypertension
    - With cyanotic heart disease
- Infants born at <35 weeks (i.e., 34 weeks, 6 days) of gestation and under 12 months of age at the start of RSV season with either congenital abnormalities of the airways or a neuromuscular disease that compromises respiratory function.

Public Comment: Christine Dubie, MedImmune – Commented that there is no new information on which these changes in AAP guidelines have been based, but rather older data that has been re-examined.

Board Decision: The Board unanimously approved the MHP recommendations noted above.

10. New Drug Product Plan Exclusions: *Diane Neal, R.Ph, (MHP)*

- Deferred to next meeting due to time constraints.

11. Updated New-to-Market Monitoring Log (Consent Agenda Topic): *Diane Neal, R.Ph, (MHP)*

- The log is posted on the web site. This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

12. General Announcements: *Diane Neal, R.Ph, (MHP)*

FDA Safety Alerts

- Acetaminophen - liver injury - FDA safety campaign
  The FDA's Center for Drug Evaluation and Research (CDER) convened a multidisciplinary working group in CDER to continue to evaluate the issues associated with acetaminophen-related liver injury and consider additional steps FDA could take to decrease the

number of cases of acetaminophen-related liver injury. The working group considered detailed reviews of the issues from the Office of Nonprescription Products, the Office of Surveillance and Epidemiology and the Division of Anesthesia and Analgesic and Rheumatology Drug Products as part of its deliberations. The working group considered the full range of options proposed and made recommendations to the Center Director regarding which should be considered for implementation. Final recommendations have not been released yet.

Public Comment: No Public Comment.

Board Decision: None needed. The FDA website will be monitored for final recommendations.

- Colchicine – now FDA approved, drug interactions, safety concerns
  The FDA has now approved the first single ingredient oral colchicine product, Colcrys®, for the treatment of familial Mediterranean fever (FMF) and acute gout flares. Oral colchicine has been used for many years as an unapproved drug with no FDA-approved prescribing information, dosage recommendations, or drug interaction warnings. During the drug application review, FDA identified safety concerns associated with the use of colchicine. Presented as information only at this time.

Public Comment: No Public Comment.

Board Decision: None needed.

- Ibuprofen – topical drug products
  The U.S. Food and Drug Administration today announced that the agency issued warning letters to eight companies marketing unlawful over-the-counter (OTC) topical drug products containing the pain reliever ibuprofen. Theses are considered unapproved new drugs. Presented as informational only.

Public Comment: No Public Comment.

Board Decision: None needed.

- Leukotriene Inhibitors – neuropsychiatric events
  The precaution section of the prescribing information for these products has been updated to include information about neuropsychiatric events reported in patients using these products. Presented as informational only.

Public Comment: No Public Comment.

Board Decision: None needed.

- Orlistat – liver injury
  The FDA is reviewing new safety information regarding reports of liver-related adverse events in patients taking orlistat. Orlistat is marketed in the United States as a prescription product, Xenical®, and as an over-the-counter (OTC) product, Alli®, both of which currently require Prior Authorization. Presented as informational only at this time until results of the review are released.

Public Comment: No Public Comment.

Board Decision: None needed.

- Propoxyphene – fatal overdoses
  The FDA is requiring manufacturers of propoxyphene-containing products to strengthen the label, including the boxed warning, emphasizing the potential for overdose when using these products. These manufacturers will also be required to provide a medication guide to patients stressing the importance of using the drugs as directed. The actions were taken because of data linking propoxyphene and fatal overdoses. Presnted as informational only.

Public Comment: No Public Comment.

Board Decision: None needed.

- Stimulant Medication in Children with ADHD
  The FDA provided its perspective on data published in the American Journal of Psychiatry on the potential risks of stimulant medications used to treat Attention-Deficit/Hyperactivity Disorder (ADHD) in children. Given the limitations of this study's methodology, the FDA is unable to conclude that these data affect the overall risk and benefit profile of stimulant medications used to treat ADHD in children. Therefore, the FDA believes that this study should not serve as a basis for parents to stop a child's stimulant medication. Parents should discuss concerns about the use of these medicines with the prescribing healthcare professional. Presented as informational only.

Public Comment: No Public Comment.

Board Decision: None needed.

- Tumor Necrosis Factor (TNF) Blockers – increased risk of lymphoma and other cancers
  FDA is requiring the manufacturers of TNF blockers to update the *Boxed Warning* in the prescribing information to alert healthcare professionals of an increased risk of lymphoma and other malignancies in children and adolescents treated with TNF blockers. Presented as informational only.

Public Comment: No Public Comment.

Board Decision: None needed.

- Xolair® - ongoing safety review
  The FDA is evaluating interim safety findings from an ongoing study of Xolair (omalizumab) that suggests an increased number of cardiovascular and cerebrovascular adverse events in a group of patients using Xolair® compared to a group of patients not given the drug (control group). This is an early communication and more information will be released later.

Public Comment: No Public Comment.

Board Decision: None needed.

13. <u>Adjourn</u>: Meeting adjourned at 9:08 p.m.

Next DUR Board Meeting
Tuesday, October 13, 2009
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.